

# **EXHIBIT 1**



## COLLABORATION AND SUPPLY AGREEMENT

This Collaboration and Supply Agreement (this "Agreement") is made effective as of the Effective Date by and between

**MSN LABORATORIES PRIVATE LIMITED**, a Company organized under the laws of India ("MSN"), with an office at MSN House, Plot No: C- 24, Industrial Estate, Sanath Nagar, Hyderabad 500018, A.P.,

AND

**NEXGEN LIFE SCIENCES, LLC** a Company having its registered office at, 8913 Regents Park Dr. Suite 550, Tampa, FL 33647, USA (hereinafter referred to as "NLS") which expression unless repugnant to the context shall mean and include its representatives, successors and assigns.

**NLS** and **MSN** may hereafter be referred to collectively as the "Parties" and individually as a "Party".

### RECITALS:

**WHEREAS** MSN has developed and is developing finished dosage formulations for various products for various countries globally; and

**WHEREAS** NLS has a sales and marketing infrastructure in the United States, and is looking to collaborate with MSN to develop, register and commercialise the Product in the Territory; and

**WHEREAS** the Parties have entered into a Non-Binding Term Sheet on 18th February 2015 agreeing on the summary of the principle understandings for entering into a definitive agreement for the Co-Development of the Product MOXIFLOXACIN (Avelox) (Oral Tablets, 400 mg); and

**WHEREAS** the Parties intend to co-operate with each other to co-develop and conduct Bio Equivalence Studies for the generic pharmaceutical product MOXIFLOXACIN (bioequivalent to Avelox® (Oral Tablets 400 mg)) and to perform validation and produce stability studies thereon to be able to comply with U.S. regulations and to establish and prepare the ANDA for submission and, upon FDA approval, for MSN to exclusively supply the finished-goods Product to NLS, all on the terms and conditions set forth in this Agreement; and

**WHEREAS**, the Parties intend to fund the Product development program to the extent set forth in this Agreement, prosecute the Product ANDA, lead any required legal or litigation strategy, and market, distribute and sell the Product in the Territory, all on the terms and conditions set forth in this Agreement; and

**WHEREAS**, it is the intention of the Parties for MSN to license to NLS certain intellectual property and know-how related to the Product and to support the filing of an ANDA for the

Product under MSN's name and, following ANDA approval, exclusively supply the Product to NLS in the Territory, all subject to the terms and conditions of this Agreement.

**NOW THEREFORE**, in consideration of the promises of each of the Parties to the other herein contained, it is mutually agreed as follows:

**1. DEFINITIONS**

- 1.1 "Act" means the Federal Food, Drug and Cosmetic Act of 1938, including any amendments thereto and all regulations promulgated thereunder or under any similar act or set of laws in the Territory.
- 1.2 "Affiliate" means, with respect to any Person, any Person which, directly or indirectly, controls, is controlled by, or is under common control with, the specified Person. For the purposes of this definition, the term "control," as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management of that Person, whether through ownership of voting securities or otherwise.
- 1.3 "ANDA" means any of the following: (i) an Abbreviated New Drug Application filed with the FDA or any similar or successor applications or procedures seeking authorization and approval to Manufacture, package, ship, and sell the Product in the United States pursuant to the Act including, without limitation, an application under 21 U.S.C. § 355(j); (ii) any other similar or equivalent FDA regulatory filing pursuant to 21 U.S.C. § 355(b)(2); (iii) any other similar or equivalent regulatory filing seeking authorization and approval to Manufacture, package, ship, and sell the Product in the Territory; and (iv) all supplements and amendments that may be filed with respect to the foregoing.
- 1.4 "ANDA Final Approval" means the granting by the FDA of final approval to NLS or any of its Affiliates, pursuant to the ANDA filed for the Product, sufficient for the marketing and First Commercial Sale of the Product in the Territory.
- 1.5 "API" means any substance or mixture of substances intended to be used in the Manufacture of a drug (medicinal) product and that, when used in the production of the drug product, becomes an active ingredient of the drug product. APIs are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease and/or symptoms of disease or to affect the structure and function of the body.
- 1.6 "Applicable Laws" means all laws, ordinances, rules and regulations applicable to the Parties' activities under this Agreement, including, without limitation, the Manufacture, Development, or Processing of API or Product, and the obligations of each Party as the context requires, including, without limitation: (i) all applicable federal, state and local laws and regulations of the Territory; (ii) the Act; and (iii) cGMPs.
- 1.7 "Average Market Share (AMS)": means the total market size of the Product within the Territory divided by the number of Approved ANDA's within the Territory for the Product.

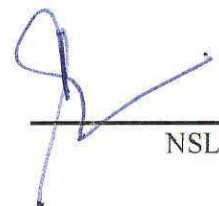


- 1.8 “Batch” means a specific quantity of the Product that is intended to have uniform character and quality within specified limits, and is produced according to a single Manufacturing order during the same cycle of Manufacture.
- 1.9 “Batch Record” means Batch production and control records as set forth in 21 C.F.R. § 211.188.
- 1.10 “Brand Name Drug” means the drug product for which a New Drug Application (“NDA”) was filed and approved by the FDA under 21 U.S.C. § 355(b)(1), and for which the NDA and Orange Book Patent(s) (if any) are held by an Innovator.
- 1.11 “Business Day” means any day that are not a Saturday, Sunday or other day on which commercial banks located in New York, New York, are authorized or required to be closed, as the case may be.
- 1.12 “Calendar Quarter” means any of the three-month periods beginning January 1, April 1, July 1 or October 1 of any calendar year.
- 1.13 “Certificate of Analysis” means a document which is signed and dated by a duly authorized representative of MSN certifying that the Product conforms to the Specifications and prepared in accordance with Section 3.11.1.
- 1.14 “cGCP” means current good clinical practices as such term is used in the Act, as or any similar set of laws, regulations, rules, or practices in the Territory or otherwise applicable to the Development, Manufacture, processing or supply of the Product and in accordance with industry practice.
- 1.15 “cGMP” or “Good Manufacturing Practices” means current good manufacturing practices as set forth in 21 C.F.R. Parts 210 and 211, as established by the FDA or any similar set of laws, regulations, rules, or practices in the Territory or otherwise applicable to Development, Manufacture, Processing or supply of Product pursuant to this Agreement.
- 1.16 “Claim” means any claim, action, suit, demand or other legal assertion or proceeding brought by a Third Party against any of the NLS Indemnified Parties and/or the MSN Indemnified Parties, as the case may be, related to any Liability.
- 1.17 “Commercialize” or “Commercialization” means the activities after receiving ANDA’S Final Approval for marketing, importing, pricing, promotion, distribution, and/or offering for sale and selling of the Product.
- 1.18 “COGs” = API + Raw Material + Packing Material + Manufacturing Cost (Conversion Cost + Analysis Cost) + Reasonable Overheads
- 1.19 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, diligent, good-faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances exercising reasonable



business judgment, it being understood and agreed that, with respect to the Manufacture, Development, Processing and Commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential as the Product, taking into account efficacy, safety, approved Labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of Regulatory Approval given the regulatory structure involved, the profitability, and other relevant factors commonly considered in similar circumstances. It is anticipated that the level of effort may change over time, reflecting changes in the status of the Product.

- 1.20 “Components” means collectively, all packaging components, raw materials, excipients, and ingredients (including labels, product inserts and other Labeling for the Product), necessary to produce the Product in accordance with the ANDA, the Drug Master File, and the Specifications for the Product.
- 1.21 “Conforming” or “Conform” means that the Product: (i) conforms, in all respects, to the applicable Specifications and DMF, Applicable Laws and the then-current edition of the U.S. Pharmacopoeia; and (ii) is not adulterated or misbranded within the meaning of the Act or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act.
- 1.22 “Controlled” means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense with respect to such Patent Rights and Know-How, of the scope of the licenses contemplated in this Agreement, or transfer such material as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party.
- 1.23 “Develop” or “Development” means any activities related to the development of the Product, including but not limited to, all formulation, process and method development, manufacturing, testing and release of all clinical/registration and scale-up, Product validation, packaging and providing for all Know How related to the Product, on-going Product stability testing in accordance with the Specifications and Applicable Laws, maintaining documentation of any stability testing conducted on the Product in accordance with the Specifications and Applicable Laws, addressing any deficiencies in connection with ANDA submissions, and any post-Launch stability testing.
- 1.24 “Drug Master File”, and its abbreviation “DMF”, with respect to the Product API, means the drug master file or any supplement thereto, filed by MSN or a Third Party with the FDA or other Regulatory Authority pursuant to the Act or other Applicable Law, which shall include the Specifications for the Product.

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- 1.25 “Development Schedule” is the schedule for Development as set forth in Section 2.3 below.
- 1.26 “Excess Demand” means the quantity of Product requested by NLS in its Firm Orders for any particular quarter that is in excess of one hundred twenty-five percent (125%) of the amount anticipated in the latest Rolling Forecast for such quarter provided to MSN.
- 1.27 “Effective Date” means the date this Agreement is signed by the last Party (as indicated by the date associated with that Party’s signature on the signature page to this Agreement).
- 1.28 “FDA” means the United States Food and Drug Administration, or any successor agency thereto.
- 1.29 “First Commercial Sale” means the first commercial sale to a Third Party of the Product in the Territory by NLS, its Affiliates and/or distributors. Sales for test marketing, clinical-trial purposes or compassionate use shall not constitute a First Commercial Sale of the Product.
- 1.30 “IFRS” means International Financial Reporting Standards, as generally and consistently applied by NLS.
- 1.31 “Innovator” means any Person having rights in an Orange Book Patent respecting a Brand Name Drug and/or the holder of the NDA, which serves as the reference listed drug for the Product ANDA.
- 1.32 “Innovator Litigation” means any patent litigation: (a) commenced by an Innovator that alleges patent infringement of an Orange Book Patent or any other patent by the Product against any MSN Indemnified Party or any NLS Indemnified Party based on: (i) the activities of NLS or MSN (including those undertaken by Affiliates on their behalf) pursuant to this Agreement related to the Product or the ANDA, or (ii) the activities of NLS or MSN (including those undertaken by Affiliates on their behalf) prior to the Effective Date related to the Product or the ANDA (including the Manufacture of the Product), or (b) commenced or joined by MSN, NLS or one of their Affiliates that seeks a judgment against an Innovator that the respective Orange Book Patent or other U.S. patent is invalid or unenforceable or that NLS, MSN, or their Affiliates have not infringed, or will not infringe, any Orange Book Patent or other U.S. patent related to the Product, in each case, irrespective of the nature of the relief sought (which may include, without limitation, actual, consequential or enhanced damages) and irrespective of the jurisdiction in which such claim, demand or action is brought.
- 1.33 “Intellectual Property Rights” means, collectively, all of the following intangible legal rights, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: (i) inventions, patents, patent disclosures, patent rights, including any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, utility model, industrial designs and design patents or any extensions thereof, (ii) rights associated with works of authorship, including without limitation, copyrights, copyright applications and copyright registrations, (iii) rights in



trademarks, trademark registrations and applications therefor, trade names, service marks, service names, logos, or trade dress, (iv) rights relating to the protection of formulae, trade secrets, Know-How and Confidential Information, and (v) all other intellectual or proprietary rights.

- 1.34 “Know-How” means any information or material in any tangible or intangible form whatsoever, including, without limitation, ideas, concepts, discoveries, inventions, developments, regulations, filings, specifications, improvements, know-how, trade secrets, designs, devices, equipment, Process conditions, algorithms, notation systems, works of authorship, computer programs, technologies, formulas, techniques, methods, procedures, assay systems, applications, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), documentation, reports, chemical compounds, products and formulations, whether patentable or otherwise.
- 1.35 “Label” means any package, packaging material, or label designed for use with the Product, pursuant to the terms of this Agreement, in accordance with Applicable Laws including the package insert for such Product, that is approved by the FDA pursuant to the terms of this Agreement.
- 1.36 “Labeling” means applying a Label or a package insert to the Product, pursuant to the terms of this Agreement, in accordance with Applicable Laws.
- 1.37 “Launch” means the First Commercial Sale in the Territory by NLS or its Affiliates or distributors.
- 1.38 “Legal Expenses” means any and all legal fees, costs and expenses incurred by NLS associated with any Third Party patent litigation in connection with the Product (including, but not limited to settlement and damage awards, court costs, attorneys’ fees and experts’ fees).
- 1.39 “Liabilities” or “Liability” means all losses, costs, damages, judgments, settlements, interest, fees or expenses including, without limitation, all reasonable attorneys’ fees, experts’ or consultants’ fees, expenses and costs, related to or arising from this Agreement or any Product developed, made, sold, marketed or otherwise distributed by the Parties.
- 1.40 “Licensed Know-How” includes any information, data and other Know-How Controlled by MSN or any of its Affiliates as of the Effective Date or any time thereafter during the Term that are necessary for or related to the Development, Manufacture, use or Commercialization of the Product in the Territory.
- 1.41 “Manufacture” or “Manufacturing” means the commercial synthesis, manufacture, storage, handling, production, Processing, packaging (including the buildup of commercial inventory), and Labeling of Product pursuant to this Agreement.
- 1.42 “Manufacturing Costs” means the sum of: (i) the cost to manufacture the Product from the Product Manufacturer; and (ii) the cost of acquiring the Product API (expressed on a

per unit basis) at the best market price then-available; and (iii) actual cost of acquiring the Components (expressed on a per unit basis).

- 1.43 “Manufacturing Facility” means the manufacturing facilities of the Product Manufacturer, or such other facility under its control that is approved by the FDA or other Regulatory Authority for manufacturing the Product and is approved in advance in writing by NLS.
- 1.44 “Marketing Approval” means the approval by the FDA of an ANDA necessary and sufficient for the marketing and First Commercial Sale of such Product in the Territory under this Agreement.
- 1.45 “Marketing Costs” means the sum of i). Domestic shipping cost ii). Warehouse costs and iii) Marketing costs. (Expressed on a per unit basis) iv). Limited Marketing warehouse overheads.
- 1.46 “Net Profits” means Net Sales less: (i) Transfer Price (ii) Marketing Costs and (ii) Additional Costs.
- 1.47 “Net Sales” means the quarterly gross sales of the Product less the following, as accrued and adjusted for amounts actually taken: (i) cash discounts and only to the extent that such amounts are included in invoices and then only to the extent that such amounts are customary and reasonable; (ii) returns (including recalls) and other credits; price protection and shelf stock adjustments; repurchase charges and other similar charges; shelf stock adjustments; slotting allowances; chargebacks, allowances, discounts, inventory management fees and rebates; (iii) other payments required by law to be made under Medicaid, Medicare or other government special medical assistance programs (including, but not limited to, payments made under the new “Medicare Part D Coverage Gap Discount Program); and (iv) sales, excise or other similar taxes (excluding income taxes); provided, however, where any such discount (or similar adjustment to Net Sales) is based on sales of a bundled set of products in which the Product is included, the discount shall be allocated to such Product on a pro rata basis based upon the sales value (i.e. the unit average selling price multiplied by the unit volume) of the Product relative to the sales value contributed by the other constituent products in the bundled set, with respect to such sale. Net Sales shall be determined in accordance with IFRS.
- 1.48 “Non-Conforming” or “Non-Conform” means that the Product does not Conform.
- 1.49 “MSN Indemnified Parties” means MSN, MSN’s Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers, employees.
- 1.50 “MSN Patents” means any patents and patent applications that are owned or controlled by MSN now or in the future related to the Development, Commercialization and Manufacture of the Product in the Territory.



- 1.51 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
- 1.52 “Process” or “Processing” mean the compounding, filling, producing and/or packaging of the API and raw materials to produce a Product in accordance with the applicable Specifications and the terms and conditions set forth in this Agreement.
- 1.53 “Product” means the generic pharmaceutical product MOXIFLOXACIN (AVELOX) (oral tablets in 400 mg dosage strengths), bioequivalent [A, AB or AP rated (as applicable)] to Avelox® and any other strengths of the Product which shall be [A, AB or AP rated and ANDA approved, in finished form ready for sale and distribution to patients including, without limitation, packaged with Labels, product inserts, Batch numbers, expiration dates, and other packaging and Labeling as set out in the ANDA and/or Specifications.
- 1.54 “Product Liability Claim” means any product liability claims or action asserted or filed by a Third Party, seeking damages or equitable relief of any kind, relating to personal injury, wrongful death, failure to warn, medical expenses, an alleged need for medical monitoring, consumer fraud or other alleged economic losses, allegedly caused by the Product, even when the same is stored strictly as per the required specifications, corroborated with documentary evidence and including claims by or on behalf of users of the Product (including spouses, family members and personal representatives of such users) relating to the use, sale, distribution or purchase of the Product sold by NLS or its Affiliates, its distributors or licensees in the Territory, and including, but not limited to, claims by Third Party payers such as insurance carriers and unions.
- 1.55 “Product Liability Costs” means all Liabilities and legal fees and expenses incurred by any MSN Indemnified Party or NLS Indemnified Party arising from an actual or alleged Product Liability Claim.
- 1.56 “Product Manufacturer” means the manufacturer of the Product.
- 1.57 “Quality Agreement” means the Quality Agreement that will govern the production of commercial Batches of the Product and that will be executed by and between NLS and the Product Manufacturer in connection with this Agreement.
- 1.58 “Regulatory Approval” means the technical, medical and scientific licenses, registrations, authorizations and approvals required for the manufacture, use, storage, import, transport, marketing, promotion, selling, and placing on the market of the Product (including post-approval changes, pricing and Third Party reimbursement approvals, and labeling approvals) by any Regulatory Authority in the Territory. This includes any authorization necessary for the development, manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of the Product as the context may require within the Territory.

- 1.59 “Regulatory Authority” means any applicable local, national or supranational government agency involved in assessing the Product or granting approvals for the marketing and sale of Product.
- 1.60 “Regulatory Filing” means any filing made with a Regulatory Authority to obtain a Regulatory Approval.
- 1.61 “NLS Indemnified Parties” means NLS, its Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers or employees.
- 1.62 “Specifications” means the file for the Product, which contains documents relating to such Product (and any other documents as agreed to by the Parties) including, without limitation: (i) written specifications for the Product API, Components and the Product; (ii) Manufacturing and packaging (primary, secondary and outer) requirements, instructions and specifications; (iii) shipping and storage requirements; (iv) all environmental, health and safety information relating to the Product API and the Product including material safety data sheets, all as updated, amended and revised from time to time by the Parties in accordance with the terms of this Agreement; (v) instructions for retained samples; (vi) quality control specifications and documentation; (vii) any other technical information necessary to carry out the contracted operations correctly in accordance with Applicable Laws and the ANDA and any other legal requirements, all as updated, amended and revised from time to time by the Parties in accordance with the terms of this Agreement; and (h) written specifications for commercial stability testing.
- 1.63 “Territory” shall mean the fifty states of the United States of America and the Commonwealth of Puerto Rico and any other territories the Parties mutually agree in writing to add to this Agreement.
- 1.64 “Third Party” means any Person other than a Party or any of its Affiliates.
- 1.65 “Transfer Price” = COGS + Transportation cost for shipping + Insurance

## 2. DEVELOPMENT SERVICES

### 2.1 Rights Granted.

- 2.1.1 MSN hereby grants to NLS and its Affiliates the right and license [with the right to sublicense] under MSN’s Intellectual Property Rights, Licensed Know-How and MSN Patents to, Commercialize, market, distribute, import, offer to sell and sell the Product in the Territory for the duration of the Term, which license shall be (a) co-exclusive with MSN with respect to the Development of the Product under and in accordance with this Agreement and (b) otherwise exclusive (even as to MSN).
- 2.1.2 MSN hereby appoints NLS as the exclusive (even as to MSN) distributor to use, market, distribute, import, offer to sell and sell the Product in the Territory for the duration of the Term.



2.2 **Development of the Product.** Subject to the allocation of responsibilities set forth in Section 2.3, the Parties shall jointly and collaboratively Develop the Product in the Territory and conduct (either by themselves or through their respective Affiliates, agents or Third Party subcontractors) all Development activities to obtain Regulatory Approval for the Product in the Territory in accordance with the terms of this Agreement. The Parties shall use Commercially Reasonable Efforts to diligently Develop the Product in accordance with the terms of this Agreement.

2.3 **Responsibilities of the Parties.**

2.3.1 **Responsibilities of MSN:**

2.3.1.1 Formulation Development (Formulation Development & Optimization, R&D Stability, Analytical Development & Validation, Method Transfer and all other related activities) for the Product.

2.3.1.2 Manufacture one Optimization & Three Exhibit batches for the Territory.

2.3.1.3 Conduct Pivotal Bio equivalent studies on the Exhibit batches, in accordance with FDA guidelines.

2.3.1.4 Conduct relevant stability studies for the Territory market as per prevalent regulatory guidelines.

2.3.1.5 Prepare manufacturing documents for filing the ANDA.

2.3.1.6 Assisting NLS in compiling the relevant documents and submitting ANDA with the Regulatory Authorities of the Territory.

2.3.1.7 Assisting NLS to receive and comply with the Regulatory Authorities of the Territory after ANDA filing and for inspection.

2.3.1.8 Obtaining and maintaining FDA approval for manufacturing facilities.

2.3.1.9 Assisting NLS in Pharmacovigilance activities.

2.3.1.10 To supply Commercial quantities of the product at mutually agreed COGs to the Territory.

2.3.1.11 MSN works hand-in-hand with NLS during the project development and welcome NLS suggestions and modifications to make the project successful.

2.3.1.12 MSN shall extend support for samples, working standards, any additional development work/information/data reasonably required and requested by the Regulatory Authorities of the Territory at no extra cost to NLS

2.3.2 **Responsibilities of NLS:**

- 2.3.2.1 Compiling the ANDA (with necessary assistance from MSN), filing the application, interacting with FDA and seeking to obtain approval for the Product ANDA which shall be in MSN's name. NLS shall be responsible for sharing any filing fees required under the Generic Drug User Fee Amendments of 2012 ("GDUFA").
- 2.3.2.2 NLS shall keep MSN informed of the status of the registration activities on a regular basis. Both Parties will communicate with each other with regard to any regulatory issues that may arise before or after the ANDA Final Approval
- 2.3.2.3 Seek to receive and comply with the Regulatory Authorities of USA after ANDA filing and for inspection.
- 2.3.2.4 Pharmacovigilance.
- 2.3.2.5 Upon receipt of all necessary Regulatory Approvals, NLS will seek to Commercialize the Product in the Territory in accordance with Applicable Law and shall use Commercially Reasonable Efforts to do so (although NLS cannot guarantee that the Product will be successfully commercialized). NLS shall handle, store and distribute Product in accordance with the Specifications and Applicable Law.

### 2.3.3 Cost Sharing between the Parties

- 2.3.3.1 API required for the total project of the product.
- 2.3.3.2 Development cost (Formulation Development & Optimization, Stability Studies and Analytical Development.
- 2.3.3.3 Analytical Validation, Method Transfer etc. related to the Product
- 2.3.3.4 Manufacturing cost of Optimization and Exhibit batches for the Product Development.
- 2.3.3.5 Pivotal BE Studies, Audit & Monitor of Pivotal BE studies
- 2.3.3.6 Stability Studies.
- 2.3.3.7 Innovator Samples
- 2.3.3.8 IP opinion (if required)
- 2.3.3.9 ANDA filing fee (50%)
- 2.3.3.10 FDA Facility Fee (50% of GDUFA Fee apportioned to total ANDA's filed (or) Products in Stability)



2.3.4 **One-Time Milestone Payments:** During the Term, NLS shall pay its share of project costing, 302,353 USD (includes cost of Pivotal Bioequivalence Study & Innovator Samples) in 3 milestone payments to MSN after completion by MSN of the corresponding milestones as mentioned below:

2.3.4.1 USD 50,000 after signing this Agreement

2.3.4.2 USD 150,000 after successful completion of Pivotal Bioequivalence Studies by MSN

2.3.4.3 USD 102,353 on ANDA filing (anticipated to be Sept 2015)

2.3.5 **Development Schedule:** The Development Schedule for the Product is set forth here under. Each Party shall be responsible to perform its Development activities within the time periods set forth in the Development Schedule. Each Party will promptly furnish to the other Party, upon its request, any and all other information relating or pertaining to the Development obligations under the Development Schedule as such Party may reasonably request from time to time:

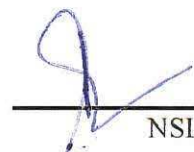
Development Stage	Time Limit
Optimization Batch Manufacturing	Completed
Exhibit Batches Manufacturing	Completed in March 2015
Stability Login	Completed in March 2015
*Pivotal BE Studies	To be Completed by April - 2015
GM Stability Completion	To be Completed by August - 2015
ANDA Filing	To be filed between August/September 2015

\* Pivotal BE shall be done with at least T 1 data on Exhibit Batches manufactured.

2.3.6 **Performance through Affiliates:** Notwithstanding anything to the contrary contained herein, each Party may discharge any obligations and exercise any right hereunder, or performance hereunder, through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

2.3.7 **Regulatory Fees:** All fees related to the filing and maintenance of the ANDA, and the costs of responding to any ANDA deficiencies shall be paid by NLS. NLS may then invoice, and MSN shall pay, fifty percent (50%) of all such costs. MSN shall pay such amounts within thirty (30) days of its receipt of such invoice.

2.3.8 **ANDA Filing & Ownership:** ANDA shall be filed in MSN's name. Both MSN and NLS shall have equal rights on the ANDA. NLS shall be responsible to make the

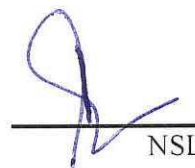
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correspondence with Regulatory Authorities of the Territory after ANDA filing and keep MSN updated on the progress at regular intervals and at any time upon the reasonable request of MSN.

- 2.3.9 **Intellectual Property and Costs:** MSN shall own all and any Intellectual Property Rights which will be generated as part of the co-development. MSN shall pay for all prosecution, filing and maintenance fees and all other related costs for any MSN Patents associated with the Product in the Territory. MSN hereby grants a license of such Intellectual Property Rights to NLS to use for its activities of filing ANDA and Commercialization of Product in the Territory. [Both parties shall have joint ownership on all other Proprietary Information and data generated pursuant to the Development of the Product-
- 2.3.10 **Intellectual Property Opinion:** MSN shall provide internal IP opinion report on Active Pharmaceutical Ingredient and Finished Dosage Form free of charge to NLS. NLS shall make its own independent IP Opinion at its own expense before entering into this Agreement.
- 2.3.11 **Legal Expenses:** NLS and MSN will equally bear the cost of legal expenses, if any, related to the ANDA filing of the Product within the Territory. [NLS and MSN shall mutually indemnify each other and Indemnify Parties harmless from and against any Liability paid or payable by the Indemnified Parties to a Third Party as a result of any Claim, insofar as such Liability or actions in respect thereof result from, arise out of or are based on any Innovator Litigation NLS shall control, through counsel of its choice, any Claim or Liability including without limitation, the right to settle. Nothing herein shall prevent a MSN Indemnified Party from retaining counsel of its choice, at such MSN Indemnified Party's sole expense, to monitor the defense, trial, or settlement of a Claim, and NLS and its counsel shall reasonably cooperate with such MSN Indemnified Party counsel.
- 2.3.12 MSN shall use Commercially Reasonable Efforts to provide all relevant information in its possession and reasonable assistance to NLS as necessary to enable NLS to defend any Innovator Litigation. MSN acknowledges and understands that such cooperation may include the retention, collection and production of documents as directed by NLS (including without limitation emails, laboratory notebooks and meeting minutes) and/or the depositions and/or trial testimony of MSN's directors, officers, employees and/or agents.

### 3. SUPPLY SERVICES

- 3.1 **Exclusive Supply.** Subject to the terms and conditions of this Agreement, MSN shall supply the Product to NLS on an exclusive basis, for distribution and sale by NLS or its Affiliates within the Territory. MSN shall be responsible for all costs related to Manufacturing the Product. The supply price of MSN to NLS shall be COGS + 10% on FOB port of destination.
- 3.2 **Firm Orders.**

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- 3.2.1 MSN agrees to supply to NLS those quantities of the Product ordered by NLS pursuant to one or more purchase orders issued in accordance with the terms and conditions hereof (each, a "Firm Order"). NLS shall issue Firm Orders to MSN for the purchase of the quantities described therein, and each Firm Order shall be considered a binding commitment upon MSN to produce and deliver such quantities on the delivery dates described therein. MSN shall confirm to NLS all Firm Orders below the Excess Demand threshold, including quantities, pricing, commercial terms, and delivery dates, in writing within five (5) business days after receipt. Any Firm Orders not expressly accepted or rejected by MSN within such time period shall be deemed to have been accepted.
- 3.2.2 NLS shall provide each Firm Order to MSN at least ninety (90) calendar days prior to the delivery date specified therein. Each Firm Order shall specify: (a) purchase order number; (b) the name and quantities of the Product to be purchased by and supplied to NLS; (c) the delivery dates and shipping instructions with respect thereto; (d) price of the Product; (e) payment terms; and (f) any other elements necessary to ensure the timely production and delivery of the Product. Each Firm Order shall constitute a contract and the Parties shall comply in all respects with the obligations set forth therein including, without limitation, the obligation of MSN to deliver the Product on the delivery date set forth in the Purchase Order; provided, however, that except for the information specified in clauses (a), (b), (c) and (f) of this Section, the supply, purchase and sale of the Products shall be governed solely by this Agreement and any additional or contrary terms or provisions contained in any Firm Order, purchase order or similar form or invoice or acknowledgment shall be void and have no force or effect.
- 3.2.3 MSN shall not be in breach of its obligations under this Agreement if it is unable to supply any Excess Demand, but MSN shall use Commercially Reasonable Efforts to supply such Excess Demand.
- 3.3 **Rolling Forecast.** Approximately three (3) months prior to NLS' anticipated Launch date of the Product, NLS shall submit to MSN a rolling twelve (12) month forecast (the "Rolling Forecast") for the period commencing on the anticipated Launch date that indicates its estimated quantities of the Product to be purchased by NLS during the 12 months following Launch. The Rolling Forecast shall be updated within the first [**five business days**] of each following month. The first two (2) months of each such Rolling Forecast shall be binding on the Parties. The remaining ten (10) months of each such Rolling Forecast shall be non-binding estimates for planning purposes and to guarantee availability of production capacity to meet NLS' forecasted requirements. The forecasts shall not be less than Average Market Share of the volumes of the Product in the Territory. NLS shall commit to purchase at least 50% of the forecast. Failure to purchase such minimum amount shall not be deemed to be a breach of this Agreement by NLS, however, if, for any reason, NLS is not able to purchase its commitments for the first two quarters, MSN will have the option to convert the NLS license granted



hereunder to semi-exclusive as follows: NLS will enable for MSN, one (1) third party label on its ANDA for MSN to supply to such third party on MSN's ANDA.

- 3.4 **Delivery Terms.** MSN agrees to deliver the Product to such locations as are designated by NLS in each Firm Order (each such shipment to be accompanied by a copy of the Firm Order submitted by NLS that corresponds to such shipment). All the Products shall be delivered to NLS in accordance with the delivery schedule specified by NLS in its Firm Orders. All domestic transportation shall be provided by NLS and coordinated with NLS' transportation manager. Terms of the shipments shall be [Ex-works (INCOTERMS® 2010)]. MSN shall provide shipment information one (1) week prior to pick up. All import transportation requirements shall be determined and communicated by NLS to MSN prior to execution of this Agreement.
- 3.5 **Shelf Life.** The entire Product must be delivered to NLS with no less than eighty-five percent (85%) of the original shelf-life. If supplied with lesser shelf life, NLS may return such Product to MSN for full reimbursement of all costs, including return shipping and handling. MSN must immediately upon notification from NLS provide replacement Product.
- 3.6 **Documents with Shipment.** With each shipment of the Product, MSN shall provide all documentation as is required by any Regulatory Authority from time to time in connection with the Manufacture, sale or exportation of the Product. If such documentation is not supplied, NLS may reject the Product.
- 3.7 **Supply Representations and Warranties.**
- 3.7.1 MSN represents and warrants that all Products supplied by MSN to NLS hereunder, and the manufacturing, packaging, labeling, storage, disposal and handling of all Product by MSN prior to delivery to NLS, shall comply with the Specifications, the applicable Regulatory Approvals, Good Manufacturing Practices and Applicable Law.
- 3.7.2 MSN covenants and agrees to provide NLS with prompt written notice of any facts or circumstances (whether occurring prior to or after the Effective Date) which cause or may cause any of the representations and warranties contained in this Section not to be true, accurate and complete as of the Effective Date or as of any date during the Term of this Agreement.
- 3.8 **Storage.** MSN shall, at all times pending shipment of Product to NLS, maintain and store all Product in accordance with the Specifications and Good Manufacturing Practices in a facility that is properly equipped (including temperature and humidity control) as required. NLS will have the right to inspect from time to time such facility and all government inspection reports and certificates relating thereto. Upon receipt by NLS of the Product, it will be NLS' sole responsibility to store the Product and maintain the data logs for the said storage conditions.
- 3.9 **Inspection and Acceptance.**



- 3.9.1 MSN will dispatch shipment of the Product to NLS as per NLS's instructions and directions. The Product shall be packaged, Labelled and marked in accordance with the Specifications.
- 3.9.2 Following receipt of a Product shipment, NLS shall, within [five (5)] business days of its receipt, carry out a visual inspection of the Product to identify any obvious defects or missing quantities.
- 3.9.3 As soon as, but in case not later than 45 days from the date of receipt of any Product by NLS from MSN, NLS shall analyze such Product either through its own Quality Control Department or through any outside agency, and shall confirm the quality of the same. NLS undertakes that once the Product passes the quality control test(s) as mentioned above, MSN shall no longer be responsible for the quality of said shipment of Product, except that MSN shall remain responsible for any hidden or latent defects which may arise after the said date, provided such Product has been stored as per the Specifications.
- 3.9.4 If any Product does not comply with the Specifications (as determined within the timeframes described in Section 3.9.3 or as determined any time thereafter in the case of hidden or latent defects), NLS shall send to MSN samples of the non-conforming or defective Product so as to enable MSN to conduct its own investigation. Any such investigations shall be completed within 30 days of receipt by MSN of such Product.
- 3.9.5 In the event MSN's investigation confirms the defect or non-conformity of the Product shipment with the Specifications, MSN shall replace the said defective Product with the Fresh batches of the same Product.
- 3.9.6 In the event of an unresolved dispute as to whether or not a Product is defective or non-conforming, the Parties shall mutually appoint an independent first class laboratory to undertake the relevant testing within sixty (60) days and its findings shall be conclusive and binding upon the Parties. All fees and expenses of the said laboratory shall be borne solely by the unsuccessful party.

3.10 **PRICE AND PAYMENT.**

- 3.10.1 **Transfer Price Adjustment.** Each anniversary of the First Commercial Sale, the Transfer Price may be increased or decreased based on an increase or decrease in MSN's Manufacturing Costs over the preceding twelve (12) month period; provided however, that any such increase shall not exceed the percentage increase in the United States Producer Price Index for Industrial Commodities during the twelve (12) month period ending on the last day of the month prior to the anniversary of the First Commercial Sale. Within twenty (20) days prior to each anniversary of the First Commercial Sale, MSN shall provide NLS with reasonable documentation of such Manufacturing Costs. NLS may audit MSN's Manufacturing Costs. An active cost improvement program as described in

Section 3.10.2 below is intended to reduce the Transfer Price through the Term and offset inflationary pressures.

3.10.2 **Continuous Improvement.** MSN and NLS agree to cooperate to identify continuous improvement opportunities with the objective to reduce Manufacturing Costs by a minimum of five percent (5%) during each twelve (12) month period during the Term of this Agreement. The price reduction target set forth in this Section 3.10.2 constitutes a goal that MSN and NLS will use Commercially Reasonable Efforts to achieve but MSN shall not be in breach of this Agreement if this target is not met despite using such Commercially Reasonable Efforts.

3.10.3 **Invoices.** Simultaneously with the shipment of any particular lot of Product to NLS, MSN shall send an invoice to NLS covering such Product. Transfer Price shall be invoiced in U.S. dollars. MSN shall reflect freight separately on each invoice for each total shipment.

3.10.4 **Payment Terms.** NLS shall pay each undisputed invoice within the later of sixty (60) days from the date of shipment either on Air Way Bill (or) Bill of Lading

3.11 **SPECIFICATIONS & QUALITY; REGULATORY MATTERS.**

3.11.1 MSN shall manufacture, supply and deliver the Product in strict conformity with the Specifications as set forth on Schedule C. *[Schedule is not attached]* Further, MSN affirms that it holds all required manufacturing authorization pursuant to the local legal requirements for the manufacture and packaging of the Product.

3.11.2 **Quality Assurance.** The Parties shall enter into a Quality Agreement for the Product within sixty (60) days from the Effective Date of this Agreement. MSN shall maintain a current Quality Agreement and quality control system compliant with the Regulatory Authority for the Product to be delivered hereunder. Such a system shall include process controls that will provide for inspection and verification of all critical parameters or operations on a regular or continuing basis throughout the manufacturing process. Each lot of Product to be supplied to NLS hereunder shall be subject to a quality control inspection by MSN in accordance with MSN's then current quality assurance standards, which standards shall be designed to ensure that each Product meets the requirements of the Specifications, Applicable Law, and the Quality Agreement, and is manufactured per Good Manufacturing Practices.

3.12 **NET PROFIT SHARING.**

3.12.1 **Net Profit Allocation Percentages.** MSN will be entitled to a payment from NLS of 50% percentage of Net Profits earned by NLS from sales of Product Commercialized during the Term pursuant to this Agreement (the "MSN Net Profit Share"). NLS shall retain the remaining 50% of such Net Profits.



3.12.2 **Net Profit Share Payments.** Net Profit allocation payments by NLS will be made on a quarterly basis within thirty (30) days after the end of the applicable Calendar Quarter, along with a report showing Net Profits, Net Sales, and deductions from Net Sales.

### 3.13 **AUDIT RIGHTS.**

3.13.1 **Records.** During the Term hereof, and for at least three (3) years thereafter (or such longer period as may be required by Applicable Law), each Party shall maintain complete and systematic written records of its business operations in connection with the manufacture, supply, and marketing, of, and Net Profits generated by, the Product.

3.13.2 **Annual Audits.** NLS shall have the right, once per 12-month period, to conduct an audit of MSN's Manufacturing Facility and records to confirm compliance with MSN's obligations hereunder. MSN shall have the right, once per 12-month period, to conduct an audit of NLS's records to confirm compliance with NLS's obligations hereunder. The auditing party shall notify the other party in writing in advance of any such audit and the Parties shall mutually determine the timing of the audit.

3.13.3 **For Cause Audits.** In addition to the audit rights described above, each Party shall also have the right to conduct "for-cause" audits of the other party at any time to address significant Product or safety concerns, Net Profit calculations or other discrepancies that are discovered related to the Product.

## 4. **COMPLAINTS; RECALLS; ADVERSE EVENTS**

4.1 **Customer Complaints and Adverse Events.** NLS or its Affiliates shall be the primary interface with customers regarding all Product complaints and inquiries and maintaining all customer complaint and adverse event files. MSN shall immediately forward to NLS any complaints or information received by MSN relating to adverse events related to the Product or related to any of the API used in the Product. NLS or its Affiliates shall be responsible for the review of the complaint or adverse event to determine the need for an investigation or the need to report to the FDA as required by Applicable Laws. At NLS's reasonable request, MSN shall promptly conduct an investigation for each Product performance or Manufacturing complaint, and shall promptly report findings and follow-up of each investigation to NLS. MSN shall make these complaint files available to NLS in the event they are required during an FDA inspection or Applicable Laws. Each Party shall reasonably cooperate with the other in sharing any information that may constitute an adverse event or complaint related to the Product.

4.2 **Product Recalls.** The Parties agree that each Party shall consult with the other Party and the Parties shall jointly cooperate in all recalls, but that NLS or its Affiliates shall be the primary interface with the Regulatory Authority and MSN shall cooperate with NLS and its Affiliates in connection with any recall. MSN shall take all appropriate corrective actions requested by NLS, and shall cooperate in any governmental investigations

  
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surrounding such recall in accordance with the procedures set forth in the Quality Agreement. In the event Product are not properly stored as per the Specifications or if the Product is recalled due to NLS's negligence then NLS shall be responsible and liable for all costs relating to such Product Recalls; otherwise MSN shall be responsible and liable for all costs relating to such Product Recalls. In the event that NLS or its Affiliates shall be required by the Regulatory Authority to recall any Product because such Product does not Conform or may violate or fail to be in compliance with any Applicable Laws or in the event that NLS or its Affiliates elect to institute a voluntary recall of the Product for health or safety reasons, NLS or its Affiliates shall be the primary coordinator.

## 5. TERM AND TERMINATION

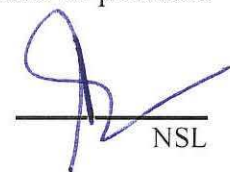
5.1 **Term.** The term of this Agreement ("Term") shall begin on the Effective Date and continue for a period of Seven (7) years from the First Commercial Sale of the Product pursuant to this Agreement. This Agreement shall thereafter be automatically renewed for consecutive one (1) year renewal terms unless a Party provides notice to the other Party at least six (6) months in advance of such renewal that such Party does not wish to renew this Agreement.

### 5.2 Termination.

5.2.1 **Termination for Cause.** Either Party may terminate this Agreement for any breach of a material provision of this Agreement by the other Party, sixty (60) days after written notice containing details of such breach, if such breach remains uncured at the end of the notice period; provided, however, that a material breach based on non-payment shall be cured within thirty (30) days of receipt of written notice. With respect to any default or breach of this Agreement, failure of a Party to provide notice to the defaulting or breaching Party as required by this Section 5.2.1 shall not constitute a waiver of the right to give such notice with respect to any subsequent default or breach.

5.2.2 **Commercial Viability.** NLS may terminate this Agreement if, with respect to the Product: (A) there is a withdrawal from the market of the Brand Name Drug due to (i) any decision, judgment, ruling or other requirement of the FDA, (ii) the issuance of a voluntary recall by FDA, (iii) the issuance of a voluntary recall by the relevant Innovator, or (iv) material safety concerns, in each case which could significantly impact the commercial viability of the Product; or (B) the 12-month rolling IMS Sales of the Brand Name Drug on the date of ANDA Final Approval are less than ten percent (10%) of such sales on the Effective Date or (C) NLS is unable to obtain ANDA Final Approval.

5.2.3 **Bankruptcy.** To the extent permitted under applicable law, either Party may terminate this Agreement effective immediately with written notice if the other Party shall file for bankruptcy, shall be adjudicated bankrupt, shall file a petition under insolvency laws, shall be dissolved or shall have a receiver appointed for substantially all of its property. All rights and licenses granted under or pursuant

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to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of MSN, NLS shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property to the extent needed to allow NLS to make or have made and continue to market and sell Product under this Agreement, and such, if not already in its possession, shall be promptly delivered to NLS by MSN, unless MSN elects to continue, and continues to perform all of its obligations under this Agreement.

### 5.3 **Effects of Termination.**

5.3.1 Upon expiration or termination of this Agreement for any reason, neither Party shall have any obligation to make any payments to the other, except for amounts accrued prior to expiration or termination, and except that a Party shall be liable to the other Party for a termination as a result of such Party's breach.

5.3.2 Upon expiration of the Term as a result of either Party providing the other Party with a notice of non-renewal (i) NLS's license to the ANDA and appointment as the exclusive (even as to MSN) distributor under the ANDA shall remain in effect on an irrevocable, perpetual, exclusive (even as to MSN), fully paid-up, and royalty-free basis, and (ii) all other licenses granted by MSN to NLS under this Agreement will terminate.

5.3.2.1 In the event of termination of this Agreement by MSN pursuant to Section 5.2.1 (Termination for Cause) or Section 5.2.3 (Bankruptcy), all licenses and rights granted by MSN to NLS or its Affiliates under this Agreement shall remain in effect on an irrevocable, perpetual, non-exclusive, fully paid-up and royalty-free basis. In such event, MSN shall, at NLS's sole expense, amend the Product ANDA to include an alternative manufacturer or supplier for the finished dosage form or API.

5.3.2.2 In the event of termination of this Agreement by NLS pursuant to Section 5.2.2 (Commercial Viability), (i) all licenses granted by MSN to NLS or its Affiliates will terminate, and (ii) NLS will promptly return to MSN all materials and records in its possession or control containing Confidential Information of MSN relating to the Product.

## 6. **REPRESENTATIONS AND WARRANTIES**

6.1 **Corporate Power.** Each Party hereby represents and warrants that such Party is duly organized and validly existing under the laws of the state of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

- 6.2 **Due Authorization.** Each Party hereby represents and warrants that such Party is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.
- 6.3 **Binding Obligation.** Each Party hereby represents and warrants that this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.
- 6.4 **Compliance with Applicable Laws.** MSN represents, warrants and covenants to NLS that it shall, at all times, (i) comply with all Applicable Laws relating to its Development of the Product and its performance of the Development Services hereunder, and (ii) discharge its obligations pursuant to this Agreement in accordance with all Applicable Laws. NLS represents, warrants and covenants to MSN that it shall, at all times, comply with all Applicable Laws relating to its Commercialization, Labeling, and sale of the Product.
- 6.5 **Notice.** Each Party covenants and agrees to provide the other with prompt written notice of any facts or circumstances (whether occurring prior to or after the Effective Date) which cause or may reasonably be expected to cause any of the representations and warranties contained in this Article 6 not to be true, accurate and complete as of the date hereof or as of any date during the Term of this Agreement.
- 6.6 **Disclaimer.** Except as set forth in this Agreement, neither Party makes any warranties with respect to the Product, express or implied, including, without limitation, as to merchantability, fitness for a particular purpose, or any other matter concerning the commercial utility of the Product.
- 6.7 **MSN Representations and Warranties.** MSN hereby represents and warrants that:
- 6.7.1 MSN owns or possesses adequate licenses or other valid rights to use all Intellectual Property Rights necessary to develop the Product in the Territory and to use, sell, offer for sale and import the Product in the Territory.
- 6.7.2 There is no actual or threatened infringement by a Third Party of any of the licensed Intellectual Property Rights, or any other infringement or threatened infringement by a Third Party that would adversely affect NLS' rights under this Agreement.
- 6.7.3 The Development, making, use and distribution of the Product as contemplated hereunder does not and will not constitute a misappropriation of the rights of any Third Party.
- 6.7.4 There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to MSN's



knowledge, threatened against MSN in connection with the Product or any licensed Intellectual Property Rights or against or relating to the transactions contemplated by this Agreement.

## 7. INDEMNIFICATION

7.1 **MSN Indemnification.** MSN shall indemnify and hold the NLS Indemnified Parties harmless from and against any Liability paid or payable by the NLS Indemnified Parties to a Third Party as a result of any Claim, insofar as such Liability or actions in respect thereof result from, arise out of or are based upon (a) any misrepresentation (or alleged misrepresentation) or breach (or alleged breach) of any of the representations, warranties, covenants or agreements made by MSN in this Agreement, or (b) the Development of any Product by MSN, or the performance of the Development Services by MSN, (c) the manufacturing, processing, supply, shipping or delivery of the Product by MSN, (d) the operation of any Manufacturing Facility, (e) any product defects with respect to the Product even when they are stored strictly as per the required specifications or (f) the negligence or willful misconduct of MSN, its officers, directors, agents, servants and employees relating to this Agreement.

7.2 **NLS Indemnification.** NLS shall indemnify and hold the MSN Indemnified Parties harmless from and against any Liability paid or payable by the MSN Indemnified Parties to a Third Party as a result of any Claim, insofar as such Liability or actions in respect thereof result from, arise out of or are based on (a) any misrepresentation (or alleged misrepresentation) or breach (or alleged breach) of any of the representations, warranties, covenants or agreements made by NLS in this Agreement, or (b) as due to its negligence, or (c) if NLS/ its affiliates do not store the Products as per the required specifications or (d) if NLS does not follow the local laws for marketing or distributing the Products within the Territory .

## 8. INSURANCE

8.1 **MSN Insurance.** MSN, at its sole cost, at all times while performing the Development work and/or any Manufacturing work and for such additional time as may be specified, maintain the appropriate insurance.

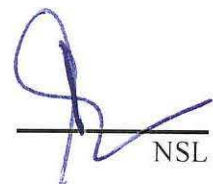
8.2 Upon commercialization of the Product MSN will maintain Product Liability insurance, including Products/Completed Operations insurance, of not less than \$5,000,000 per occurrence and \$5,000,000 per accident for bodily injury and personal injury, including death, and property damage, and \$5,000,000 in the aggregate. This policy must be maintained in full force and effect for an additional three (3) years following the expiration or termination of this Agreement; and

8.3 **NLS Insurance.** NLS shall (at its sole cost and expense) maintain a program of insurance or self-insurance that is customary of companies in the same or similar business.

## 9. CONFIDENTIALITY



- 9.1 Obligations. Each Party acknowledges that it may receive confidential or proprietary information of the other Party in the performance of this Agreement. Each Party shall use Commercially Reasonable Efforts to safeguard and to hold such information received by it from the other Party in confidence, and shall limit disclosure of the furnishing Party's information to those employees and consultants of the receiving Party and its Affiliates who are informed of and understand the confidential nature thereof and are bound by non-disclosure and non-use obligations no less restrictive than those set forth in this Agreement. To the extent that such employees or consultants take an action, or fail to take an action, that would constitute a breach of such confidentiality or non-use obligations by such employee or contractor (as if such employee or contractor were a party to this Agreement), it will constitute a breach of such obligations as if a Party had taken, or failed to take, such action itself. Neither Party shall, directly or indirectly, disclose, publish or use for the benefit of any Third Party or itself, except in carrying out its duties hereunder or as otherwise provided in this Article 9, any confidential or proprietary information of the other Party, without first having obtained the furnishing Party's written consent to such disclosure or use. "Confidential Information" shall include Know-How, scientific information, clinical data, efficacy and safety data, formulas, methods and processes, specifications, pricing information (including discounts, rebates and other price adjustments), the terms and conditions of this Agreement, and other terms and conditions of sales, customer information, business plans, and all other intellectual property. This restriction shall not apply to any information within the following categories: (i) information that is known to the receiving Party or its Affiliates prior to the time of disclosure to it, to the extent evidenced by written records or other competent proof; (ii) information that is independently developed by employees, agents, or independent contractors of the receiving Party or its Affiliates without reference to or reliance upon the information furnished by the disclosing Party, as evidenced by written records or other competent proof; (iii) information disclosed at any time to the receiving Party or its Affiliates by a Third Party that has a right to make such disclosure; or any other information that is or becomes part of the public domain through no fault or negligence of the receiving Party.
- 9.2 Required Disclosures. The receiving Party shall also be entitled to disclose the other Party's Confidential Information (i) that is required to be disclosed in compliance with applicable laws or regulations (including, without limitation, to comply with SEC, NASDAQ or stock exchange disclosure requirements) or by order of any governmental body or a court of competent jurisdiction, (ii) as may be necessary or appropriate in connection with the enforcement of this Agreement, or (iii) as may be necessary for the conduct of clinical studies; provided, however, that the Party disclosing such information shall promptly notify the other Party and shall use Commercially Reasonable Efforts to obtain confidential treatment of such information by the agency or court or other discloser, and that, in the case of disclosures under (i), shall (a) provide the other Party with prompt prior notice of the proposed disclosure such that the other Party may seek a protective order or other appropriate remedy, and (b) provide the other Party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon.

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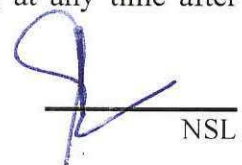
- 9.3 Use of Information. Each Party shall use, and direct each of its Affiliates to use, any Confidential Information obtained by it from the other Party or their respective Affiliates, pursuant to this Agreement or otherwise, solely in connection with the transactions contemplated hereby.
- 9.4 Relief. Each Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security, enjoining or restraining any other Party from any violation or threatened violation of this Article.
- 9.5 Return of Information. Upon the earlier of expiration or termination of this Agreement, each Party shall, if requested by the other Party, return or destroy all Confidential Information of such other Party and copies and extracts thereof; provided, that the Parties shall not be required to return or destroy any electronic copy of Confidential Information created pursuant to its standard electronic backup and archival procedures. Notwithstanding the foregoing, each Party may retain one copy of any Confidential Information of the other Party to the extent required to defend or maintain any litigation relating to this Agreement, comply with legal or regulatory requirements or established document retention policies, or to demonstrate compliance with this Agreement. Notwithstanding the return or destruction of the Confidential Information (or the retention of any Confidential Information pursuant to the preceding sentence) the Parties shall continue to be bound by its obligations of confidentiality and non-use hereunder. Each Party's obligations of confidentiality and non-use shall extend for a period of five years from the expiration or termination of this Agreement.
- 9.6 Publicity. Neither Party shall, without the prior written consent of the other Party, disclose to Third Parties, nor originate any publicity, news release or public announcement, written or oral, whether to the public, the press, stockholders or otherwise, referring to the terms or existence of this Agreement, the subject matter to which it relates, the performance under it or any of its specific terms and conditions, except such announcements, as in the opinion of the counsel for the Party making such announcement, are required by law, including United States securities laws, rules or regulations or any securities exchange. If MSN decides to make an announcement it believes to be required by law with respect to this Agreement, it will give NLS advance written notice of the announcement, including the text of such announcement, and an opportunity to comment upon such announcement.

## 10. GENERAL

- 10.1 Exclusivity. During the Term of this Agreement, MSN and its Affiliates will not Develop the Product for or with any Third Party that could reasonably be expected to manufacture, market, sell, or distribute the Product in the Territory, and shall not license any MSN Patents, Intellectual Property or Licensed Know-How about the Development of the Product to any Third Party for such use in the Territory. During the Term of this Agreement, MSN and its Affiliates will also not themselves market, sell, or distribute the Products in the Territory.



- 10.2 Informal Dispute Resolution. Unless otherwise expressly provided for herein, any claim or controversy between the Parties arising out of or relating to the execution, interpretation and performance of this Agreement (including the validity, scope and enforceability of this provision) shall be identified in writing and presented to the other Party. Within fourteen (14) days after delivery of such notice of dispute, the NLS Executive Officer and the MSN Executive Officer shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute in good faith. All reasonable requests for information made by one Party to another shall be honored. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such Executive Officers cannot resolve such dispute within fourteen (14) days after such meeting, then each Party reserves its right to any and all remedies available under law or equity with respect to any other dispute.
- 10.3 Injunctive Relief. Either Party may seek immediate injunctive or other interim equitable relief as necessary to enforce the terms of this Agreement, provided that such relief is sought exclusively from a court as provided in Section 10.4 hereof. The Parties hereto acknowledge and agree that any breach of the terms of this Agreement could give rise to irreparable harm for which money damages would not be an adequate remedy and accordingly the Parties agree that, in addition to any other remedies, each Party shall be entitled to obtain preliminary or injunctive relief and to enforce the terms of this Agreement by a decree of specific performance without payment of a bond or surety.
- 10.4 Jurisdiction. MSN and NLS agree to irrevocably submit to the exclusive jurisdiction of (i) the courts of the State of New Jersey, U.S.A., or (ii) the United States District Court for the State of New Jersey, U.S.A., for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the State of New Jersey, U.S.A. or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the courts of the State of New Jersey, U.S.A. . Each Party hereto agrees that any such proceeding shall be conducted solely in the English language.
- 10.5 Convictions, Exclusion, Debarment, Etc. MSN represents and warrants to NLS that neither MSN nor any person employed by or under contract to MSN now or in the future in connection with any work to be performed for or on behalf of NLS, including without limitation, any services performed hereunder (i) has been convicted of an offense related to any Federal or State healthcare program, including (but not limited to) those within the scope of 42 U.S.C. § 1320a-7(a); (ii) has been excluded, suspended or is otherwise ineligible for Federal or State healthcare program participation, including (but not limited to) persons identified on the General Services Administration's List of Parties Excluded from Federal Programs or the HHS/OIG List of Excluded Individuals/Entities; (iii) has been debarred from or under any Federal or State healthcare program (including, but not limited to debarment under Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC 335a); or (iv) is on any of the FDA Clinical Investigator enforcement lists, including, but not limited to, the (a) Disqualified/Totally Restricted List, (b) Restricted List and (c) Adequate Assurances List. MSN further agrees that if, at any time after

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execution of this Agreement, it becomes aware that it has or any person who participated, or is participating, in the performance of any service or any other work for NLS has become or is in the process of being charged, convicted, debarred, excluded, proposed to be excluded, suspended or otherwise rendered ineligible, or is on an enforcement list, MSN will immediately notify NLS in writing.

- 10.6 Governing Law. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of Florida, U.S.A. applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any Party's performance hereunder.
- 10.7 WAIVER OF JURY TRIAL. Each Party hereto waives, to the extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement, and each Party hereto (i) certifies that no representative, agent or attorney of any other party has represented, expressly or otherwise, that such other Party would not, in the event of litigation, seek to enforce that foregoing waiver, and (ii) acknowledges that it and the other Party hereto has been induced to enter into this Agreement by, among other things, the mutual waivers and certifications.
- 10.8 Assignment or Transfer of Interest. This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the Parties and may not be assigned or transferred by a Party (other than to an Affiliate) without the prior written consent of the other, except that such consent shall not be required on the part of either Party in connection with a merger or acquisition of a controlling interest in the equity securities, or acquisition of a substantial portion of the assets of that Party, by a Third Party, provided that the successor or assignee assumes all of the obligations imposed herein. Any attempted assignment that does not comply with the terms of this Section 10.8 shall be void.
- 10.9 Force Majeure. Provided that such failure is cured as soon as is practicable after its occurrence, the failure of MSN or NLS to perform any of its obligations under this Agreement, other than the payment of amounts invoiced, shall not subject MSN or NLS to any liability, if such failure is caused or occasioned by an event of force majeure, including but not limited to, any actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, national industry strikes, lockouts, sabotage, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control of the non-performing Party. The Party claiming force majeure shall notify the other Party with notice of the force majeure event as soon as practicable, but in no event later than fourteen (14) days after its occurrence, which notice shall reasonably identify such obligations under this Agreement and the extent to which performance thereof will be affected. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such force majeure



event, and the Party affected by the force majeure event shall use all reasonable efforts to minimize the loss or inconvenience suffered by the Parties.

- 10.10 No Consequential Damages. To the extent permitted by Applicable Law, neither Party shall be entitled to recover from the other Party any special, incidental, consequential or punitive damages in connection with this Agreement except to the extent that a Party is solely seeking reimbursement for such damages paid to a Third Party and such reimbursement is covered by the indemnification provisions of this Agreement, or as otherwise expressly provided hereunder.
- 10.11 Entire Agreement. This Agreement, including any schedules or exhibits hereto, contains the entire agreement and understanding between the Parties relating to the subject matter hereof, and shall supersede all prior or contemporaneous agreements and understandings, oral or written, relating to the subject matter hereof (including, but not limited to, any Term Sheet) and any inconsistent terms of any subsequent invoice, purchase order or similar document. Neither Party shall be liable or bound to the other Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein.
- 10.12 Amendments and Waiver. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Parties. By an instrument in writing a Party may waive compliance by another Party with any term or provision of this Agreement that such other Party was or is obligated to comply with or perform. Any failure of a Party to enforce at any time, or for any time period, any of the provisions of this Agreement shall not be deemed or construed to be a waiver of such provisions or a waiver of any right of such Party thereafter to enforce each and every such provision on any succeeding occasion or breach thereof.
- 10.13 Further Actions and Documents. Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.
- 10.14 Notices. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (i) on the date delivered, if personally delivered, (ii) on the date sent by telecopies with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (iii) on the Business Day after being sent by FedEx or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery, or (iv) five (5) Business Days after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable Party at the address set forth below; provided that a Party may change its address for receiving notice by the proper giving of notice hereunder:

  
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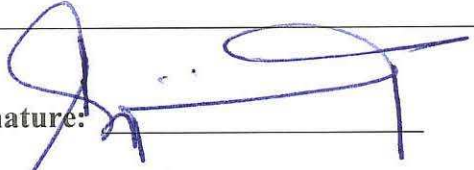
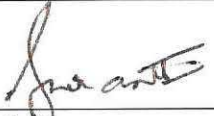
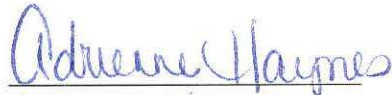


If to MSN:	If to NLS:
<b>Name : C. Bharat Reddy</b> <b>Designation : Executive Director</b>	<b>Name: Suren Ajjarapu, Managing Member</b>
Name Plot No: C-24, Industrial Estate Sanathnagar, Hyderabad, 500018, Telangana	<b>8913 Regents Park Dr. Suite # 680, Tampa, FL-33647 USA</b>
Address India.	

- 10.15 Counterparts; Facsimile/PDF Signature. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may also be executed via facsimile or PDF, which shall be deemed an original. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.
- 10.16 Severability. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefore of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; provided, however, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto shall be enforceable to the fullest extent permitted by law.
- 10.17 Headings. The captions or headings of the Sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and are not part of the agreement of the Parties and shall have no effect on the meaning of the provisions hereof. All references in this Agreement to Sections or Articles are to Sections or Articles of this Agreement, unless otherwise indicated.
- 10.18 Expenses. Each Party will pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement.
- 10.19 Third Party Rights. Nothing in this Agreement will be deemed to create any Third Party beneficiary rights in or on behalf of any other Person, other than NLS Indemnified Parties and MSN Indemnified Parties.

10.20 Survival. The Parties' respective rights and obligations under the following Sections and Articles (and all associated definitions) shall survive the termination or expiration of this Agreement: Article 1 (Definitions), Section 2.3.9 (Intellectual Property and Costs), Section 3.11 (Specifications and Quality; Regulatory Matters), Article 4 (Complaints; Recalls; Adverse Events), Article 6 (Records; Inspections; Audits), Article 5 (Term and Termination), Article 7 (Indemnification), Article 8 (Insurance), Article 9 (Confidentiality) and Article 10 (General).

IN WITNESS WHEREOF, each Party is signing this Agreement on the date stated opposite that Party's signature.

<b>FOR MSN LABORATORIES PRIVATE LIMITED</b>	<b>FOR NEXGEN LIFE SCIENCES, LLC</b>
<b>Signature:</b>  <b>Name:</b> C. Bharat Reddy <b>Designation:</b> Executive Director	<b>Signature:</b>  <b>Name:</b> Suren Ajjarapu <b>Designation:</b> Managing Member
<b>Witness:</b>  <b>Signature:</b> _____ <b>Name:</b> Srikanth Gurram <b>Designation:</b> Sr. GM – Business Development	<b>Witness:</b>  <b>Signature:</b> _____ <b>Name:</b> Adrienne Haynes <b>Designation:</b> _____
<b>Date:</b> _____	<b>Date:</b> 04.30.2015





**ANNEXURE 1 TO GENERIC FINISHED PHARMACEUTICAL FORMULATION TERM SHEET BETWEEN  
NEXGEN LIFE SCIENCES & MSN LABORATORIES PRIVATE LIMITED**

**MSN Laboratories Private Limited**, a company incorporated under the Companies Act, 1956, having its registered office at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad – 500018, A.P (hereinafter referred to as **MSN**)

And

**NEXGEN LIFE SCIENCES, LLC** a company having its Registered Office at 8913, Regents Park Dr. Suite 550, Tampa, FL 33647, USA (hereinafter referred to as "**NLS**") which expression shall include its successors and permitted assigns), of the Second Part.

Whereas NLS and MSN have concluded a Generic Finished Pharmaceutical Formulation Term Sheet regarding MOXIFLOXACIN HYDROCHLORIDE (PRODUCT) dated 18<sup>th</sup> day of February 2015 (AGREEMENT) and Executed Master Co-Development and Distribution agreement on April 29, 2015.

The parties agree to add **ANNEXURE 1** to the Generic Finished Pharmaceutical Formulation Term Sheet of MOXIFLOXACIN HYDROCHLORIDE and include two further PRODUCTS named **CAPECITABINE** Oral Tablets 150mg and 500mg and **ROSUVASTATIN CALCIUM** Oral Tablets 40mg, 20mg, 10mg, 5mg.

The parties agree to add **ANNEXURE – 1A** which is the Development Plan and Timelines for **CAPECITABINE** Oral Tablets 150mg and 500mg for the Generic Finished Pharmaceutical Formulation Term Sheet.

Formulation Development	:	Completed
Pilot BE Completion	:	BE Waiver
PO Batch Manufacturing	:	Apr-2015
PV Batches Manufacturing	:	Apr-2015
Pivotal Stability Login	:	May-2015
Pivotal BE Studies	:	BE Waiver
6M Stability Completion	:	Nov/Dec-2015
ANDA Completion	:	Dec-2015/Jan-2015

The parties agree to amend **ADDENDUM A – 1B** which is the Development Plan and Timelines for **ROSUVASTATIN CALCIUM** Oral Tablets 40mg, 20mg, 10mg, 5mg. for the Generic Finished Pharmaceutical Formulation Term Sheet.

Formulation Development	:	Completed
Pilot BE Completion	:	Completed
PO Batch Manufacturing	:	Apr-2015
PV Batches Manufacturing	:	Apr-2015
Pivotal Stability Login	:	May-2015
Pivotal BE Studies	:	June/Jul-2015
6M Stability Completion	:	Nov/Dec-2015
ANDA Completion	:	Dec-2015/Jan-2015

The parties agree to add **ANNEXURE – 1C** of CAPECITABINE for the Generic Finished Pharmaceutical Formulation Term Sheet.

**ANNEXURE – 1C is Cost of Development of the ANDA** for **CAPECITABINE** Oral Tablets 150mg and 500mg

API Quantity Estimated for Entire Project	:	338.91 Kg
API cost Per Kg (USD)	:	\$ 900
TOTAL API COST (USD)	:	\$ 305,019
Development Cost (USD)	:	\$ 158,500
Manufacturing Cost (USD)	:	\$ 132,000
TOTAL COST (USD)	:	\$ 595,519
PER PARTY COST (USD)	:	\$ 297,760

**NOTE :**

1. The cost of Tangible Items like Innovator Samples, RM, PM, Columns, Change Parts etc are at actuals and shall be shared by both parties equally.
2. Stability Studies of Intermediate Conditions will be done if 40oCG/75% RH fails and the cost of such studies shall be shared by both parties equally.
3. As CAPECITABINE is eligible to apply for BE Waiver being BCS Class-I drug, BE studies cost is not considered, if required, shall be shared equally by both parties.

MSN

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NLS





**TENTATIVE COGs of CAPECITABINE**

500mg – BOTTLE – 120s – 54.44 USD

150mg – BOTTLE – 60s – 8.89 USD

The parties agree to add **ANNEXURE – 1D** of ROSUVASTATIN CALCIUM for the Generic Finished Pharmaceutical Formulation Term Sheet.

**ANNEXURE – 1D is Cost of Development of the ANDA** for ROSUVASTATIN CALCIUM Oral Tablets 40mg, 20mg, 10mg, 5mg.

API Quantity Estimated for Entire Project	: 48.90 Kg
API cost Per Kg (USD)	: \$ 4,000
TOTAL API COST (USD)	: \$ 195,624
Development Cost (USD)	: \$ 235,000
Manufacturing Cost (USD)	: \$ 211,000
TOTAL COST (USD)	: \$ 641,624
PER PARTY COST (USD)	: \$ 320,812

**NOTE :**

1. The cost of BE studies, BE Audit & Monitoring are at actuals and shall be shared by both parties equally.
2. The cost of Tangible Items like Innovator Samples, RM, PM, Columns, Change Parts etc are at actuals and shall be shared by both parties equally.
3. Stability Studies of Intermediate Conditions will be done if 40oCG/75% RH fails and the cost of such studies shall be shared by both parties equally.

**TENTATIVE COGs of ROSUVASTATIN CALCIUM**

5mg – BOTTLE – 90s – 3.38 USD

10mg – BOTTLE – 90s – 5.16 USD

15mg – BOTTLE – 90s – 8.97 USD

20mg – BOTTLE – 30s – 5.53 USD

NLS shall pay its share of project costing, 297,760 USD in four milestone payments for **CAPECITABINE** Oral Tablets 150mg and 500mg as mentioned below.

1. 50,000 USD after signing this Annexure.
2. 150,000 USD after completion of 6 months Stability Studies

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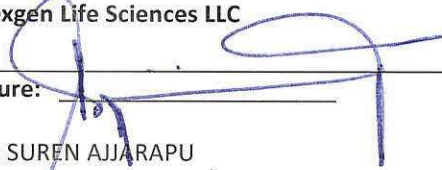

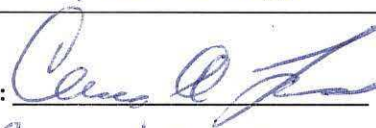
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3. 50,000 USD on ANDA filing
4. 47,760 USD on FDA acceptance of ANDA for review
5. 50% of Tangible Items cost on ANDA filing
6. 50% of Annual GDUFA Facility Fee (Around 13,827 USD)
7. 50% of ANDA Filing Fee (Around 32,000 USD)

NLS shall pay its share of project costing, 320,812 USD in four mile stone payments for **ROSUVASTATIN CALCIUM** Oral Tablets 40mg, 20mg, 10mg, 5mg as mentioned below.

1. 50,000 USD after signing this Annexure
2. 175,000 USD on completion of Pivotal Bioequivalent Studies
3. 50,000 USD on ANDA filing
4. 45,812 USD on FDA acceptance of ANDA for review
5. 25% of total cost of Bioequivalent (BE) Studies on the date of initiation of BE studies and 25% of total cost on completion of BE studies.
6. 50% of total Tangible Items cost on ANDA filing
7. 50% of Annual GDUFA Facility Fee (Around 27,654 USD)
8. 50% of ANDA Filing Fee (Around 32,000 USD)

The other contractual terms of the Term Sheet remain unchanged.

For MSN Laboratories Private Limited	For Nexgen Life Sciences LLC
Signature: 	Signature: 
Name: C BHARAT REDDY	Name: SUREN AJJARAPU
Designation: EXECUTIVE DIRECTOR	Designation: MANAGING MEMBER
Place: Hyderabad, India	Place: Tampa/FL. USA
Date: 4 <sup>th</sup> May 2015	Date: 04.30.2015
Witness:	Witness:
Signature: 	Signature: 
Name: SRIKANTH GURRANI	Name: Carole Lucas
Designation: SENIOR GENERAL MANAGER	Designation: VP of Operations
Place: HYDERABAD, INDIA	Place: Tampa, FL USA
Date: 4 <sup>th</sup> May 2015	Date: 04/30/2015